BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2017-10
Wholesale Drug License and)
CSA Registration of) COMBINED STATEMENT OF
_) CHARGES, SETTLEMENT
WEEKS & LEO CO., INC.,) AGREEMENT, AND FINAL ORDER
License No. 5039)
Registration No. 2100090)
Respondent.)
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COME NOW the lowa Board of Pharmacy ("Board") and Weeks & Leo Co., Inc. ("Respondent"), 2075 NW 92nd Ct, Clive IA 50325, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2017), and 657 IAC 36.6. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, 155A, and 272C, and 657 IAC chapters 10 and 36.

A. STATEMENT OF CHARGES

COUNT I UNAUTHORIZED DISTRIBUTION

1. Respondent is charged with the distribution of drugs for other than lawful purposes, specifically distributing drugs in violation of lowa Code sections 124.212(4)(c), 124.302(2), 124.401(1), 124.402(1)(b), and 657 IAC 17.7, and may be disciplined pursuant to lowa Code sections 124.304(1)(d) and 155A.17(2), and 657 IAC 10.12(1)"d", 17.18, 36.1(4)"h", and 36.1(4)"u".

COUNT II

OPERATING WITHOUT A CURRENT LICENSE

2. Respondent is charged with operating a wholesale drug facility without a current wholesale drug license in violation of Iowa Code section 155A.17(1) and 657 IAC 17.3, and may be disciplined pursuant to Iowa Code section 155A.17(2) and 657 IAC 17.18 and 36.1(4)"v".

COUNT III

FAILURE TO PERFORM ANNUAL INVENTORY

3. Respondent is charged with failing to take a new inventory of all stocks of controlled substances on hand at least annually in violation of 657 IAC 10.35(3), and may be disciplined pursuant to Iowa Code section 124.304(1)(d), and 657 IAC 10.12(1)"d", 36.1(4)"u", and 36.1(4)"ac".

COUNT IV INADEQUATE SECURITY

4. Respondent is charged with failing to have adequate physical security controls as required by 657 IAC 10.15(1), and may be disciplined pursuant to lowa Code section 124.304(1)(d), and 657 IAC 10.12(1)"d" and 36.1(4)"u".

COUNT V

INCOMPLETE RECEIPT AND DISBURSEMENT RECORDS

5. Respondent is charged with failing to include the DEA registration number of purchasers and sellers on receipt and disbursement records in violation of 657 IAC 10.34(4), and may be disciplined pursuant to Iowa Code section 124.304(1)(d), and 657 IAC 10.12(1)"d", 36.1(4)"u", and 36.1(4)"ac".

B. FACTUAL CIRCUMSTANCES

- 6. Respondent holds lowa wholesale drug license number 5039, which is currently active through December 31, 2017.
- 7. Respondent holds controlled substances registration number 2100090, which is currently active through May 31, 2018.
- 8. Respondent engaged in the repackaging of pseudoephedrine products into unit dose packaging.
- 9. Respondent was inspected in February of 2017. The following deficiencies were observed:
 - a. Respondent permitted employees to use monthly credits to purchase pseudoephedrine products and to take rejected blister cards of pseudoephedrine products.
 - b. Respondent sold pseudoephedrine products to at least one location that did not have the authority to possess controlled substances.
 - c. Respondent's wholesale drug license had expired on December 31, 2016.
 - d. Annual inventories for pseudoephedrine products were not available for the years 2015 and 2016.
 - e. Pseudoephedrine products were routinely left unsecured.
 - f. Invoices did not contain the DEA registration numbers for entities shipping pseudoephedrine products to Respondent or for entities receiving pseudoephedrine products from Respondent.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

- 10. The Board has jurisdiction over the parties and the subject matter of these proceedings.
- 11. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.
- 12. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
- 13. Respondent acknowledges that it has the right to be represented by counsel on this matter.
- 14. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
- 15. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
- 16. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
 - 17. This Order shall not be binding as to any new complaints received by the Board.
- 18. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.
- 19. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.
 - 20. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

21. Respondent agrees to **VOLUNTARILY SURRENDER** its lowa wholesale drug license and controlled substances registration to resolve this matter.

- 22. Respondent shall transfer any controlled substances that are required by law to be retained to another entity with legal authority to possess the controlled substances.
- 23. This voluntary surrender is considered discipline and, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15. Respondent agrees not to perform any activities that would require an lowa wholesale drug license or controlled substances registration unless its license and registration are reinstated.
- 24. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 124, 155A, and 272C and 657 IAC chapters 10 and 36.

This Co	mbi	ned	Statement	of	Cha	arges,	Settler	nent	Agr	eement,	and	Final	Order	is \	olunta/	rily
submitt	ed	by	Responden	t	to	the	Board	for	its	conside	ratio	on on	the	15	day	of
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Patrick A. Neile Rall
WEEKS & LEO CO., INC.
Respondent

By this signature, <u>Patrick A. Neibergall</u> acknowledges s/he is the <u>Vice President</u> for Weeks & Leo Co., Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Weeks & Leo Co., Inc.

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the lowa Board of Pharmacy on the $\frac{28}{3}$ day of $\frac{3000}{3}$, 2017.

Chairperson

Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Office of the Attorney General of Iowa 1305 E. Walnut St. Des Moines, IA 50319 ATTORNEY FOR THE STATE